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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,746	11/21/2003	Vladimir I. Slepnev	19781/2062	3146

7590 06/26/2006

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/719,746	Applicant(s) SLEPNEV, VLADIMIR I.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/04, 10/04, 4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status

1. Claims 1-40 are pending and considered for examination in this office action.

Priority

2. This application filed on November 21, 2003 claims benefit of US provisional 60/439,982 filed on 01/14/2003 and 60/428,038 filed on 11/21/2002.

Information Disclosure Statement

3. The Information Disclosure Statement filed on February 02, 2004, October 22, 2004 and April 24, 2006 have been entered and considered.

Objection to Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the application contains informal drawing sheets. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the at least on block" in line 1 of the claim 4. There is insufficient antecedent basis for this limitation in the claim. Claim 4 depends on claim 1 which lacks support for said limitation, hence the meets and bounds of the claim 4 is indefinite and unclear as it lacks support in the claim 1 upon which it depends. Amendment to recite proper dependency would obviate the rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-13, 15-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Haff et al. (US 5,720,923).

Haff et al. teach a polymerase chain reaction (PCR) apparatus of claims 1, 27, 32, 35, comprising

(i) a solution holder (capillary tubes) separately hold plurality of samples of reaction mixture (see col. 3, line 1-6, col. line 19-64); (ii) a heat exchanging structure to cyclically control specified duration and temperature of plurality of samples (see col. 3, line 6-15, col. 4, line 19-51); and an aliquot dispensing mechanism to dispense samples (see col. 4, line 24-25, line 56-60, col. 16, line 56-58, col. 19, line 56-67, col. 20, line 1-7).

With regard to claim 2, Haff et al. teach that the set of plural samples comprises all of the plural samples (see col. 4, line 31-35).

With regard to claims 3-5, 13, Haff et al. teach that the sample holder comprises heat-conducting metal block which comprises aluminum block (see col. 4, line 19-21, col. 15, line 54-63, col. 18, line 34-55).

With regard to claims 6-7, Haff et al. teach that the solution holder comprises any material such as glass (silica material and multiple capillary tubes (see col. 16, line 34-36).

with regard to claims 8-11, Haff et al. teach that the capillary tubes comprise one end closed by sealing the ends or having oil at either end or with valves (see col. 15, line 2-11, col. 17, line 45-64).

With regard to claim 12, Haff et al. teach that plural samples comprise multiple of 96 samples (see col. 4, line 31-35).

With regard to claims 15, Haff et al. teach that the heat exchanging structure comprises at least one water bath (see col. 11, line 1-36).

With regard to claim 16-20, Haff et al. teach that the temperatures comprise two or three

incubation temperatures comprising denaturation of 80-90⁰ C, annealing of 45-65⁰ C and extension of 60-75⁰ C (see col. 3, line 46-65).

With regard to claims 21-24, Haff et al. teach that the apparatus comprises loading apparatus to load samples and aliquot holders comprise 96 well microtiter plates (see col.18, line 65-67col. 19, line 1-25).

With regard to claims 25-26, haff et al. teach that the aliquot holders comprise one of sample holders and sample inputs of another instrument (see col. 4, line 3-6).

With regard to claim 27-28, 30-34, 36-37, Haff et al. teach a polymerase chain reaction (PCR) apparatus further comprises automatic dispensing mechanism (see col. 4, line 56-67, col. 19, line 56-67, col. 20, line 1-67).

With regard to claim 29, Haff et al. teach that the apparatus comprises a reaction system to cause amplification (see col. 18, line 34-55).

With regard to claim 32, 35, 38, Haff et al. teach that the apparatus comprises a separation and quantitation device to analyze aliquots in the aliquot holders (see col. 25, line 17-55).

Accordingly the disclosure of Haff et al. anticipates the instant claims.

B. Claims 1-4, 6-9, 11-14, 16, 19, 21-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahil et al. (WO 00/66995).

Cahil et al. teach a polymerase chain reaction (PCR) apparatus of claim 1, comprising (i) a solution holder separately hold plurality of samples of reaction mixture (see page 11, line 4-30, page 12. line 1-19, page 17, line 1-8); (ii) a heat exchanging structure to cyclically control specified duration and temperature of plurality of samples (see page 11, line 14-21, page 12, line 1-19); and an aliquot dispensing mechanism to dispense samples (see page11, line 22-30, page

12, line 9-19, page 15, line 16-24, page 17, 14-20).

With regard to claim 2, Cahil et al. teach that the set of plural samples comprises all of the plural samples (see page 9, line 26-27).

With regard to claims 2-4, 13, Cahil teach that the sample holder comprises heat-conducting metal block (see page 13, line 21-31).

With regard to claims 6-8, Cahil et al. teach that the solution holder comprises silica coated material and multiple capillary tubes (see page 13, line 21-31, page 15, line 25-31).

with regard to claims 8-9, 11, Cahil et al. teach that the capillary tubes comprise one end closed by sealing the ends or with valves (see page 6, line 15-25, page 20, line 14-18).

With regard to claim 12, Cahil et al. teach that plural samples comprise multiple of 96 samples (see page 9, line 26-27).

With regard to claims 14, Cahil et al. teach that the heat exchanging structure comprises at least on hot air oven (see page 20, line 14-25).

With regard to claim 16, 19, Cahil et al. teach that the temperatures comprise two or three incubation temperatures (see page 10, line 28-32 indicating denaturation, annealing and incubation temperatures).

With regard to claims 21-24, Cahil et al. teach that the apparatus comprises loading apparatus to load samples and aliquot holders comprise 96 or 384 well microtiter plates (see page 7, line 28-32, page 17, line 14-16, page 22, line 10-26).

With regard to claims 25-26, Cahil et al. teach that the aliquot holders comprise one of sample holders and sample inputs of another instrument (see page 20, line 1-32, page 21, line 1-7).

With regard to claim 27-28, 30-37, Cahil et al. teach a polymerase chain reaction (PCR) apparatus comprising

(i) a solution holder separately hold plurality of samples of reaction mixture (see page 11, line 4-30, page 12, line 1-19, page 17, line 1-8); (ii) a heat exchanging structure to cyclically control specified duration and temperature of plurality of samples (see page 11, line 14-21, page 12, line 1-19); and (iii) an automatic dispensing mechanism to automatically dispense samples (see page 11, line 22-30, page 12, line 9-19, page 15, line 16-24, page 17, line 14-20).

With regard to claim 29, Cahil, et al. teach that the apparatus comprises a reaction system to cause amplification (see page 22, line 10-32, page 23, line 1-5, page 20, line 26-32).

With regard to claim 32, 35, 38-40, Cahil et al. teach that the apparatus comprises a separation device (capillary electrophoresis) to analyze aliquots in the aliquot holders (see page 10, line 3-14, page 16, line 18-20, page 28, line 1-6). Accordingly the disclosure of Cahil et al. anticipates the instant claims.

C. Claims 1-4, 13, 21-24 are rejected under 35 U.S.C. 102(a) as being anticipated by Tal et al. (USPN. 6,482,615).

Tal et al. teach a polymerase chain reaction (PCR) apparatus of claim 1 comprising (i) a solution holder separately hold plurality of samples of reaction mixture (see col. 2, line 51-67, col. 4, line 54-67); (ii) a heat exchanging structure to cyclically control specified duration and temperature of plurality of samples (see col. 2, line 51-67, col. 4, line 48-56); and an aliquot dispensing mechanism to dispense samples (see col. 5, line 34-46).

With regard to claims 2-4, 13, Tal et al. teach that the sample holder comprises heat-conducting metal block (see col. 4, line 51-67, col. 10, line 22-24).

With regard to claims 21-24, Tal et al. teach that the apparatus comprises loading apparatus to load samples and aliquot holders comprise 96 or 384 well microtiter plates (see col. 8, line 10-12). Accordingly the instant claims are anticipated by Tal. et al.

D. Claims 1-4, 13, 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Tal et al. (USPN. 6,482,615).

Tal et al. teach a polymerase chain reaction (PCR) apparatus of claim 1 comprising (i) a solution holder separately hold plurality of samples of reaction mixture (see col. 2, line 51-67, col. 4, line 54-67); (ii) a heat exchanging structure to cyclically control specified duration and temperature of plurality of samples (see col. 2, line 51-67, col. 4, line 48-56); and an aliquot dispensing mechanism to dispense samples (see col. 5, line 34-46).

With regard to claims 2-4, 13, Tal et al. also teach that the sample holder comprises heat-conducting metal block (see col. 4, line 51-67, col. 10, line 22-24).

With regard to claims 21-24, Tal et al. teach that the apparatus comprises loading apparatus to load samples and aliquot holders comprise 96 or 384 well microtiter plates (see col. 8, line 10-12). Accordingly the instant claims are anticipated by Tal. et al.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Patent Examiner,
Art Unit 1637

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU
PATENT EXAMINER 6/22/06